510(k) SUMMARY

JUL 0 3 2013

This 510(k) Summary information is submitted in accordance with the requirements of 21 CFR § 807.92.

510(k) Number: K123983

Submitter:

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Date Prepared:

June 27, 2013

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Device Identification

Trade Names: FastPack® Vitamin D Immunoassay
FastPack® Vitamin D Calibrator Kit
FastPack® Vitamin D Control Kit
FastPack® Vitamin D Method Verification Kit

Common Names: Vitamin D Assay
Vitamin D Calibrator
Vitamin D Controls
Vitamin D Verifiers

Classification names: System, Test, Vitamin D
Calibrator
Quality control material (assayed and unassayed)

Classifications:	Class II (assay) Class II (calibrators) Class I, reserved (controls) Class I, reserved (verifiers)
Panel:	Chemistry (75)
Product Codes:	MRG - Vitamin D test system JIT - Calibrator, Secondary JJX - Single (specified) Analyte Controls (Assayed and Unassayed)
Regulation Numbers:	21 CFR § 862.1825 - Vitamin D test system 21 CFR § 862.1150 - Calibrator 21 CFR § 862.1660 - Quality control material (Assayed and Unassayed)

Devices to Which Substantial Equivalence is Claimed

LIAISON® 25 OH Vitamin D TOTAL Assay
DiaSorin Inc.
1951 Northwestern Avenue
PO Box 285
Stillwater, MN 55082-0285
K112725

Device Description

The FastPack® Vitamin D Immunoassay employs a competitive immunoassay principle. Endogenous Vitamin D in a patient sample, calibrator, control, or verifier is mixed with pretreatment buffer then added into a FastPack® reagent pack. In the reagent pack, the pre-treated Vitamin D sample binds with a monoclonal (mouse) anti-Vitamin D antibody covalently linked to alkaline phosphatase (ALP). After incubation, a conjugate of Vitamin D-Biotin linked to streptavidin coated paramagnetic particles is added. Monoclonal anti-Vitamin D antibody-ALP conjugate not reacted with Vitamin D in the sample will bind to unoccupied binding sites of the Vitamin D-biotin conjugate bound to the streptavidin paramagnetic particles. After washing steps (using a Tris buffer containing detergents) to separate bound from unbound anti-Vitamin D monoclonal antibody-ALP, a chemiluminogenic substrate mixture is added to the system. This mixture contains indoxyl-3-phosphate, a substrate for ALP, and lucigenin (N,N'-dimethyl-9,9'-biacridinium dinitrate). ALP dephosphorylates indoxyl-3-phosphate to

indol-3-ol, which subsequently undergoes oxidation. As a result, lucigenin is reduced to form a dioxetane structure that is cleaved to yield N-methylacridone. This compound produces a sustained luminescent glow following excitation. The raw relative luminescence units (RLUs) generated are measured by a photomultiplier tube in the FastPack® Analyzer and are inversely proportional to the concentration of Vitamin D in the sample. The entire reaction sequence takes place at 37 ± 0.5 °C and is protected from external light.

Intended Use

FastPack® Vitamin D Immunoassay is intended for the quantitative determination of total 25-hydroxyvitamin D and other hydroxylated metabolites in human serum and plasma. The assay is to be used as an aid in the assessment of vitamin D sufficiency in adults. The FastPack® Vitamin D Immunoassay is intended for use with the FastPack® Analyzer.

The FastPack® Vitamin D Calibrator Kit is used for calibrating the quantitative FastPack® Vitamin D Immunoassay on the FastPack® Analyzer.

FastPack® Vitamin D Control Kit is used for quality control of the FastPack® Vitamin D Immunoassay on the FastPack® Analyzer.

FastPack® Vitamin D Method Verification Kit is used in the quantitative verification of calibration and assay range of the quantitative FastPack® Vitamin D Immunoassay on the FastPack® Analyzer.

Comparison of new device to predicate devices

Similarities between FastPack® and LIAISON® Vitamin D Assays

CHARACTERISTIC	Qualigen FastPack® Vitamin D Immunoassay	DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay (K112725)
Intended Use/ Indications for Use	for the *in-vitro* quantitative determination of total 25-hydroxyvitamin D and other hydroxylated metabolites in human serum and plasma. The assay is to be used as an aid in the assessment of vitamin D sufficiency in adults. The FastPack® Vitamin D Assay is intended for use with the FastPack® Analyzer.	for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated vitamin D metabolites in human serum to be used in the assessment of vitamin D sufficiency. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions in an adult population.
Sample Type	Serum or plasma (lithium-heparin or EDTA)	Serum only
Sample Preparation	Standard processing for serum or plasma	Standard processing for serum
Assay principle	Chemiluminescence	Chemiluminescence
Approximate run time	10 minutes	20 minutes
Interpretation of Results	Standard Curve	Standard Curve
Reagent Storage Temperature	2-8 °C	2-8 °C
Methodology	The FastPack® Vitamin D Immunoassay is a direct competitive chemiluminescence immunoassay employing paramagnetic particles.	The DiaSorin LIAISON 25 OH Vitamin D TOTAL Assay is a direct competitive chemiluminescence immunoassay employing paramagnetic particles.
Testing Environment	Professional use	Professional use
Precision	Within-run: ≤ 15.1 Between-run: ≤ 4.9% Total: ≤ 15.1	Within-run: ≤ 7.7% Between-run: ≤ 3.2% Total: ≤ 12.6%
Linearity	Assay linear from LOQ (12.9 ng/mL) to 150 ng/mL	Assay linear from LOQ (4.0 ng/mL) to 150 ng/mL
Interfering Substances	No interference from high levels of bilirubin, hemoglobin,	No interference from high levels of bilirubin,

	cholesterol, lipids, total protein, and biotin	hemoglobin, triglycerides, uric acid, IgG, albumin, and cholesterol
Cross-reactivity	~100% cross-reactivity with 25-OH D2, 25-OH D3, and 24,25-(OH)2-Vitamin D3; <10% cross-reactivity with Vitamin D2, Vitamin D3, 1,25-(OH)2-Vitamin D2, 1,25-(OH)2-Vitamin D3, 3-epi-25(OH) Vitamin D3, 24,25-(OH)2-Vitamin D2, and Paricalcitol	~100% cross-reactivity with 25 OH D2, 25 OH D3; <10% cross-reactivity with Vitamin D2, Vitamin D3, 3-epi-25OH Vitamin D3, 1,25-(OH)2-Vitamin D2, and 1,25-(OH)2-Vitamin D3
Comparative Testing vs Established Methods	N = 137 Range of observations: 18.6 to 132.6 ng/mL Deming regression to LIAISON: Slope (95% CI): 0.97 (0.88-1.06) y (95% CI): -4.6 (-8.9 to -0.25) R (95% CI) = 0.92 (0.90-0.94) Sy|x = 10.3	N = 587 Range of observations: 4.0 to 150.0 ng/mL Linear regression to radioimmunoassay: Slope (95% CI): 1.047 (1.02-1.07) Y (95% CI): 2.41 (1.43-3.40) R = 0.936

Differences between FastPack® and LIAISON® Vitamin D Assays

CHARACTERISTIC	**Qualigen FastPack® Vitamin D Immunoassay**	**DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay (K112725)**
Platform	FastPack® Analyzer	LIAISON® Analyzer
Assay procedure	Automated	Automated
Traceability	Internal standards (9 levels) assigned based on patient correlation with LIAISON® 25 OH Vitamin D TOTAL Assay.	Standardized using UV quantification of 25-(OH) Vitamin D

Similarities between FastPack® and LIAISON® Vitamin D Calibrators

CHARACTERISTIC	Qualigen FastPack® Vitamin D Calibrator Kit	DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay (K112725)
Intended Use/Indication for Use	For in-vitro diagnostic use in calibrating FastPack® Vitamin D Immunoassay	Similar
Storage temperature	2-8 °C	2-8 °C in the dark
Matrix	Human serum-based matrix containing preservative and stabilizers	Human serum-based matrix containing preservative

Differences between FastPack® and LIAISON® Vitamin D Calibrators

CHARACTERISTIC	Qualigen FastPack® Vitamin D Calibrator Kit	DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay (K112725)
Antigen used in calibrators	No antigen present	Antigen present
Number of calibrators	1	2
Open vial stability	60 days	4 weeks

Similarities between FastPack® and LIAISON® Vitamin D Controls

CHARACTERISTIC	Qualigen FastPack® Vitamin D Control Kit	DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay (K112725)
Intended Use/Indication for Use	For in-vitro diagnostic use to monitor the precision and accuracy of the FastPack® Vitamin D Immunoassay on the FastPack® Analyzer.	For use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay.
Antigen used in controls	25-(OH) vitamin D	Same
Matrix	Human serum-based matrix containing preservative and stabilizers	Human serum-based matrix containing preservative
Number of levels	2	Same
Storage temperature	2-8 °C	Same

Differences between FastPack® and LIAISON® Vitamin D Controls

CHARACTERISTIC	Qualigen FastPack® Vitamin D Control Kit	DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay (K112725)
Open vial stability	30 days	No open vial stability claimed

Similarities between FastPack® and LIAISON® Vitamin D Verifiers

CHARACTERISTIC	Qualigen FastPack® Vitamin D Method Verification Kit	DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay (K112725)
Intended Use/Indication for Use	For in-vitro diagnostic use to monitor the precision and accuracy of the FastPack® Vitamin D Immunoassay on the FastPack® Analyzer.	For use as assayed quality control materials intended for in vitro diagnostic use in the quantitative verification of calibration and reportable range of the Liaison 25 OH Vitamin D Total Assay when performed on the Liaison Analyzer.
Antigen used in Verifiers	25-(OH) vitamin D	Same
Matrix	Human serum-based matrix containing preservative and stabilizers	Human serum-based matrix containing preservative
Storage temperature	2-8 °C	Same
Open vial stability	Single Use - NA	4 weeks

Differences between FastPack® and LIAISON® Vitamin D Verifiers

CHARACTERISTIC	Qualigen FastPack® Vitamin D Method Verification Kit	DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay (K112725)
Number of levels	3	4

Performance Summary

Precision

Precision was evaluated following the CLSI EP5-A2 guidance. Four samples with concentrations of ~25, ~30, ~45, and ~80 ng/mL were tested in duplicate determinations in each of two runs per day on each of two FastPack® Analyzers, each paired with an individual FastPack® Reagent lot over a period of 20 days to yield 160 replicate determinations of each sample (80 replicates per lot/analyzer). Within-run, between-run,

and between-day components of variation were calculated as well as total imprecision using a fully nested 2-way random factor ANOVA model with runs nested within days. The tables below present the results by instrument/reagent combination:

Analyzer 1, Reagent Lot 1

		Within-Run		Between-Run		Between-Day		Total	
	Average	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Sample 1	27.3	2.8	10.2	1.3	4.9	1.9	7.1	3.7	13.4
Sample 2	31.1	3.3	10.7	0.0	0.0	1.8	5.7	3.8	12.1
Sample 3	45.5	3.9	8.5	0.0	0.0	2.0	4.3	4.3	9.5
Sample 4	84.9	4.1	4.8	0.0	0.0	3.2	3.7	5.1	6.1

Analyzer 2, Reagent Lot 2

		Within-Run		Between-Run		Between-Day		Total	
	Average	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Sample 1	25.9	3.9	15.1	0.0	0.0	0.0	0.0	3.9	15.1
Sample 2	32.7	3.7	11.2	0.0	0.0	2.0	6.0	4.2	12.7
Sample 3	46.1	3.5	7.5	0.0	0.0	1.2	2.6	3.7	7.9
Sample 4	76.4	3.2	4.1	0.0	0.0	1.7	2.3	3.6	4.7

Limits of blank, detection, and quantitation

The Limit of Blank (LOB), the Limit of Detection (LOD), and the Limit of Quantitation (LOQ) of the FastPack® Vitamin D Immunoassay were determined according to CLSI EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation. The following are the limits determined:

LOB = 2.3 ng/mL
LOD = 6.2 ng/mL
LOQ = 12.9 ng/mL

Linearity

Linearity was determined following CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: a Statistical Approach: Approved Guideline. A high patient sample was intermixed with a low sample to generate 9 concentration levels each tested in duplicate determinations. Linear results were compared to 2nd and 3rd order polynomial fits against a pre-specified allowable error of ± 5 ng/mL. The linearity range was found to extend from the LOQ (12.9 ng/mL) to 150.0 ng/mL.

Cross-reactivity

Two samples containing low and high concentrations of Vitamin D were tested without and with added concentrations of potential cross-reacting compounds including 1,25-dihydroxy Vitamin D2; 1,25-dihydroxy Vitamin D3; Vitamin D2; Vitamin D3; 25-hydroxy Vitamin D2; 25-hydroxy Vitamin D3; 24,25-dihydroxy Vitamin D2; 24,25-dihydroxy Vitamin D; 3-epi-25-hydroxy Vitamin D3, and Paricalcitol. Maximum cross-reactivity at the indicated cross-reactant concentration tested was determined for each compound.

Compound	Concentration (ng/mL)	% Cross-Reactivity
Vitamin D2	500	2.0
Vitamin D3	500	1.9
1,25-(OH)2-Vitamin D2	100	4.0
1,25-(OH)2-Vitamin D3	100	9.8
3-epi-25(OH) Vitamin D3	400	7.8
25 (OH) Vitamin D2	100	93.0
25 (OH) Vitamin D3	25	106.0
Paricalcitol	200	-1.2
24, 25 (OH)2 Vitamin D2	40	-0.9
24, 25 (OH)2 Vitamin D3	20	117.4

Interferences

The following substances normally present in blood were tested and found not to interfere in the FastPack® Vitamin D Immunoassay at the noted concentrations:

Bilirubin	Tested to 40 mg/dL
Biotin	Tested to 1000 ng/mL
Cholesterol	Tested to 500 mg/dL
Total Protein	Tested to 10.7 g/dL
Hemoglobin	Tested to 500 mg/dL
Lipids	Tested to 250 mg/dL

Serum and plasma equivalence

Blood collections were obtained from 32 volunteers and processed in parallel to serum EDTA plasma, and lithium-heparin plasma. Measurements in FastPack® Vitamin D Immunoassay were compared via Deming regression and indicated equivalence between the three matrices.

Serum versus EDTA plasma

Parameter	Result
N compared	32
Range of observations, ng/mL	Serum: 17.4 - 139.5 Plasma: 14.9 - 134.1
Absolute bias, ng/mL	-6.7
% Bias	-11.1
Regression results	
Slope	0.993
y-intercept	-6.3
R	0.979
R^2	0.959

Serum versus lithium-heparin plasma

Parameter	Result
N compared	32
Range of observations, ng/mL	Serum: 17.4 - 139.5 Plasma: 18.1 - 133.3
Absolute bias, ng/mL	-2.5
% Bias	-4.1
Deming regression results	
Slope	0.970
y-intercept	-0.7
R	0.971
R^2	0.943

Expected Values/Reference Intervals

To determine a reference interval, serum samples from 367 subjects were acquired from 4 different sources representing 5 different geographic regions of the United States. Sampling took place during the period of February - May 2013, representing a range of exposures to sunlight based on the geographic regions of sampling and to the transition of weather conditions from Winter to Spring to early Summer. Samples were acquired only from subjects in the range of 21-90 years of age, with no family or personal history of

parathyroid disease, thyroid disease, calcium regulatory disease; and no personal history of kidney disease, gastrointestinal disease, liver disease, seizures, chronic disease, or bariatric surgery. Additionally, subjects were not taking any medications that might interfere with Vitamin D absorption. Lastly, subjects were restricted to < 2000 IU/day of Vitamin D supplementation. The results indicated a reference interval of 13.7 - 57.3 ng/mL based on the non-parametric 2.5^{th} - 97.5^{th} percentiles.

Observed values	
Mean	27.6 ng/mL
Median	24.2 ng/mL
2.5^{th} - 97.5^{th} percentile	13.7 - 57.3 ng/mL

Method Comparison

Human serum samples were tested with the FastPack® Vitamin D Immunoassay and the obtained results were compared to the predicate method. A total of 137 samples ranging from 18.6 to 132.6 ng/mL were tested in both assays. The FastPack® Vitamin D Immunoassay correlated well with the predicate method with correlation coefficient (R) of 0.92, slope = 0.97, and y-intercept = -4.6 ng/mL.

Parameter	Result
Slope (95% CI)	0.97 (0.88 - 1.06)
y-intercept (95% CI)	-4.6 (-8.9 to -0.25)
R (95% CI)	0.92 (0.90 - 0.94)
Range of values	18.6 - 132.6 ng/mL

SUMMARY

The information provided in this pre-market notification indicates that the FastPack® Vitamin D Immunoassay is substantially equivalent to the stated predicate device. The information further indicates that the FastPack® Vitamin D Immunoassay is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 3, 2013

Qualigen, Inc.
C/O Michael Poirier
2042 Corte Del Nogal, Suite B
CARLSBAD CA 92009

Re: K123983
Trade/Device Name: FastPack® Vitamin D Immunoassay
FastPack® Vitamin D Calibrator Kit
Fastpack® Vitamin D Control Kit
FastPack® Vitamin D Method Verification Kit
Regulation Number: 21 CFR 862.1825
Regulation Name: Vitamin D test system
Regulatory Class: II
Product Code: MRG, JIT, JJX
Dated: May 31, 2013
Received: June 3, 2013

Dear Mr. Poirier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123983

Device Name: Device Name:

FastPack® Vitamin D Immunoassay
FastPack® Vitamin D Calibrator Kit
FastPack® Vitamin D Control Kit
FastPack® Vitamin D Method Verification Kit

Indications for Use:

FastPack® Vitamin D Immunoassay is intended for the quantitative determination of total 25-hydroxyvitamin D and other hydroxylated metabolites in human serum and plasma. The assay is to be used as an aid in the assessment of vitamin D sufficiency in adults. The FastPack® Vitamin D Immunoassay is intended for use with the FastPack® Analyzer.

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FastPack® Vitamin D Method Verification Kit is used in the quantitative verification of calibration and assay range of the quantitative FastPack® Vitamin D Immunoassay on the FastPack® Analyzer.

Prescription Use __√__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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